

No. MIIXR0002EAC

TOSHIBA

DICOM CONFORMANCE STATEMENT

**MEDIA STORAGE
FOR
TOSHIBA DIGITAL FLUOROGRAPHY SYSTEM**

MODEL DFP-2000A

with XIDF-037A and XIDF-038A

or

SRS-1000A

(MIIXR0002EAC)

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1 Introduction

This document is a DICOM Conformance Statement for Toshiba's Digital Fluorography Systems. It is intended to provide the reader with the knowledge of how to integrate this product within DICOM compliant equipments. It details the DICOM Service Classes, Information Objects, and Application Profiles which are supported by this product.

If the reader is unfamiliar with DICOM, it is recommended that they read the DICOM Specification (referenced below) prior to reading this conformance statement. Also note that this document is formatted according to the DICOM Specification, Part 2: Conformance.

1.1 References

- ACR-NEMA Digital Imaging and Communications in Medicine, DICOM V3.0.

1.2 Definitions

- **Information Object Definition (IOD)** - An IOD is a data model which is an abstraction of real-world information. This data model defines the nature and attributes relevant to the class of real-world objects represented.
- **Service/Object Pair (SOP) Class** - A SOP Class is defined by the union of an Information Object Definition and a set of DIMSE Services. A DICOM Application Entity may support one or more SOP Classes. Each SOP Class is uniquely identified by a SOP Class UID.
- **SOP Instance** - A specific occurrence of a Information Object.
- **Transfer Syntax** - The Transfer Syntax is a set of encoding rules that allow DICOM Application Entities to negotiate the encoding techniques (e.g. data element structure, byte ordering, compression) they are able to support.
- **Unique Identifier (UID)** - A Unique Identifier is a globally unique, ISO compliant, ASCII-numeric string. It guarantees uniqueness across multiple countries, sites, vendors and equipment.

1.3 Acronyms, Abbreviations and Symbols

- ACC American College of Cardiology
- ACR American College of Radiology
- ASCII American Standard Code for Information Interchange
- AE Application Entity
- ANSI American National Standards Institute
- AP Application Profile
- CEN TC251 Comite Europeen de Normalisation - Technical Committee 251 - Medical Informatics
- DICOM Digital Imaging and Communications in Medicine
- FSC File-set Creator
- FSR File-set Reader
- FSU File-set Updater
- IOD Information Object Definition
- ISO International Standards Organization
- JIRA Japan Industries Association of Radiological Systems
- NEMA National Electrical Manufacturers Association
- RWA Real-World Activity
- SOP Service-Object Pair
- UID Unique Identifier

2 Implementation Model

2.1 Application Data Flow Diagram

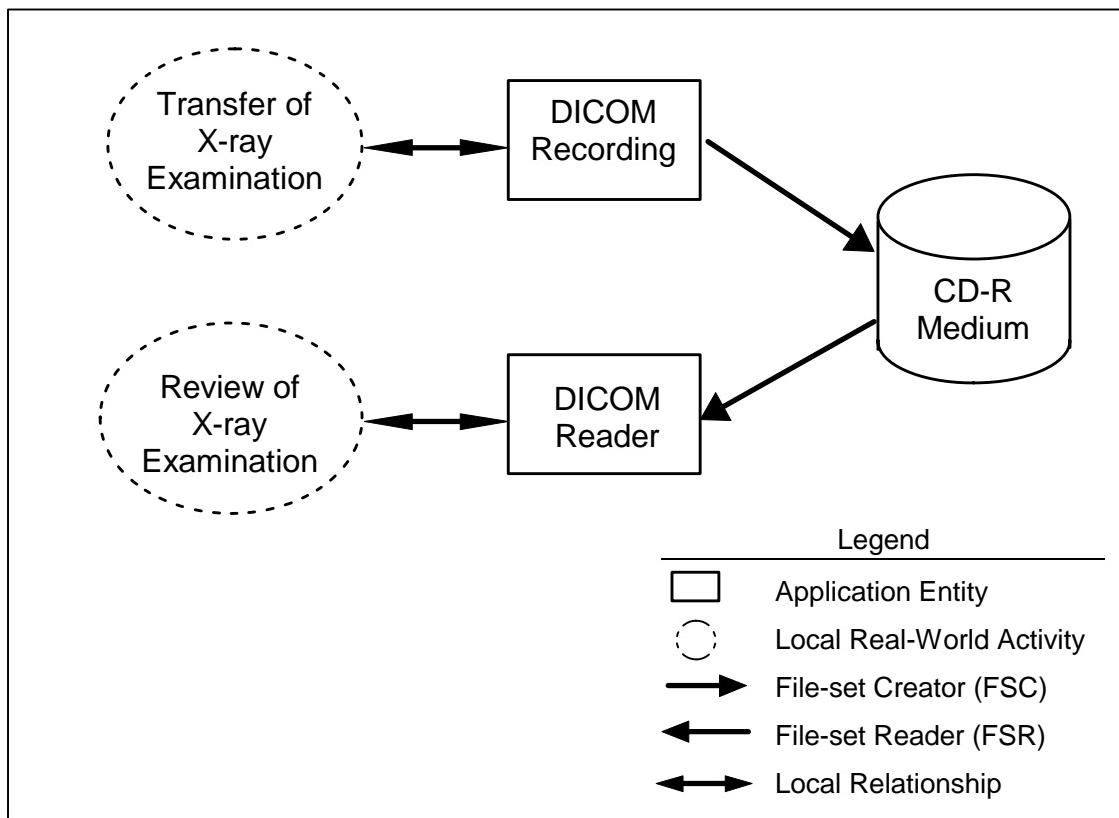


Figure 1

2.2 Functional Definitions of AE's

2.2.1 DICOM Recording

The DICOM Recording supports the following tasks:

- Builds DICOM XA Information Objects.
- Creates a DICOMDIR file that represents the contents of DICOM XA Information Objects to be recorded.
- Records DICOM XA Information Objects and DICOMDIR from the local storage to the CD-R media.
- Duplicates the File-set of the CD-R media or the local storage onto the blank CD-R media.

2.2.2 DICOM Reader

The DICOM Reader supports the following tasks:

- Reads the DICOMDIR file that represents the contents of the data as recorded.
- Displays the ordered list of patient and image identifying information or icon images.
- Reads the selected image SOP instance from the CD-R media and displays it on the monitor of the DICOM Reader.
- Reads the File-set of the CD-R media and writes it onto the local storage of DICOM Reader.

2.3 Sequencing of Real World Activities

2.3.1 Features

2.3.1.1 Transfer of X-ray Examination

- Operator requests to transfer images to the local storage after selecting the transferred images from the Patient List or from the Image List.
- Operator requests to record the images of the local storage onto the CD-R media after transferring all data that are to be recorded.
- When the size of images exceeds the capacity of a single CD-R, the request of transferring images is canceled.
- Each CD-R media has a DICOMDIR file that represents the contents of the data as recorded.
- Operator can request to duplicate the CD-R media from the recorded CD-R media to the blank CD-R media

2.3.1.2 Review of X-ray Examination

- Operator inserts the CD-R media to be read.
- Operator requests to display the list of images or the catalog of icon images that are recorded on the CD-R media.
- Operator selects one image from the list or from the thumbnail images and requests to review the image from the CD-R media.
- Operator can request to read images from the CD-R media onto the local storage and then operator can request to review the image from the local storage.
- Operator can request to delete the images on the local storage.
- The images on the local storage remain after being recorded onto the CD-R media, so operators can display these images from the local storage also.

2.3.2 Operation

2.3.2.1 Transfer of X-ray Examination

- The operation for manual transfer of X-ray examination is described below:

STEP-1: Select the images or the patient to be transferred.

STEP-2: Request transfer.

STEP-3: Insert the blank CD-R media.

STEP-4: Request recording the transferred images onto the CD-R media.

2.3.2.2 Review of X-ray Examination

- The operation for manual review of X-ray examination is described below:

STEP-1: Insert the CD-R media to be review.

STEP-2: Select one image from the list or from the thumbnail images.

STEP-3: Request forward play, backward play, step by step, or other image processings.

2.4 File Meta Information for Implementation Class and Version

- File Meta Information Version 0x0001
- Implementation Class UID 1.2.392.200036.9116.31
- Implementation Version Name TM_XA_DCM_V12

3 AE Specifications

3.1 DICOM Recording Specification

The DICOM Recording AE provides Standard Conformance to the DICOM Media Storage Service, File Format Class and the Media Storage Application Profile.

Table 1

Application Profile	Identifier	Real World Activity	Role	SC Option
Basic Cardiac X-ray Angiographic Studies on CD-R Media	STD-XABC-CD	Transfer of X-ray Examination	FSC	Interchange
1024 X-ray Angiographic Studies on CD-R Media	STD-XA1K-CD	Transfer of X-ray Examination	FSC	Interchange

3.1.1 File Meta Information for the Application Entity

The Application Entity Title is registered into the DICOM File Meta Information header.

- Source Application Entity Title TM_XA_DCM_V12

3.1.2 Real-World Activity

3.1.2.1 Real-World Activity - Transfer of X-ray Examination

DICOM Recording AE acts as a FSC when chosen by the operator. This AE writes the SOP instances onto the CD-R media, creates a DICOMDIR and writes it onto the CD-R media.

3.1.3 Media Storage Application Profile

DICOM Recording AE uses the Application Profile defined in Table 1.

3.1.4 Information Object Definition and DICOMDIR keys

Information Object Definition and DICOMDIR keys are described in Chapter 8.

3.2 DICOM Reader Specification

The DICOM Reader AE provides Conformance to the DICOM Media Storage Service, File Format Class and the Media Storage Application Profile.

Table 2

Application Profile	Identifier	Real World Activity	Role	SC Option
Basic Cardiac X-ray Angiographic Studies on CD-R Media	STD-XABC-CD	Review of X-ray Examination	FSR	Interchange
Extended Cardiac X-ray Angiographic Studies on CD-R Media	AUG-XABC-CD	Review of X-ray Examination	FSR	Interchange

3.2.1 File Meta Information for the Application Entity

The Application Entity Title is not relevant because this DICOM Reader AE only reads CD-R media.

3.2.2 Real-World Activity

3.2.2.1 Real-World Activity - Review of X-ray Examination

DICOM Reader AE acts as a FSR when chosen by the operator. This AE reads the DICOMDIR from the CD-R media and reads the SOP instances from the CD-R media.

3.2.3 Media Storage Application Profile

DICOM Reader AE uses the Application Profile defined in Table 2.

3.2.4 Information Object Definition and DICOMDIR keys

Information Object Definition and DICOMDIR keys are described in Chapter 8.

4 Augmented and Private Application Profiles

4.1 Augmented Application Profiles

DICOM Reader AE supports Augmented Application Profile: AUG-XABC-CD.

This is a extension of the standard Application Profile: STD-XABC-CD.

4.1.1 AUG-XABC-CD

4.1.1.1 SOP Class Augmentations

None

4.1.1.2 Directory Augmentations

None

4.1.1.3 Other Augmentations

The following attributes used within the X-ray Angiographic Image files have the specified values.

Table 3

Attribute Name	Tag	Value
Modality	(0008, 0060)	XA
Rows	(0028, 0010)	1024
Columns	(0028, 0011)	1024
Bits Allocated	(0028, 0100)	8
Bits Stored	(0028, 0101)	8

4.2 Private Application Profiles

Not applicable to this product.

5 Extensions, Specializations, and Privatizations of SOP Classes and Transfer Syntaxes

Not applicable to this product.

6 Configuration

For the Digital Fluorography System, the configuration can be set.

Note: Settings and changes are performed by Toshiba Service Personnel at the time of installation of the Digital Fluorography System.

7 Support of Extended Character Sets

This product supports the following character sets:

Table 4

• ISO-IR 6 (default)	Basic G0 Set
----------------------	--------------

8 X-Ray Angiographic Information Object Definition

8.1 Entity Module Definitions

The information modules for the X-Ray Angiographic devices are defined below.

8.1.1 Media Storage Directory IOD Modules

Table 5

Object	Module / key	Reference	Usage ¹
DICOM File Meta Information		8.2.1	M
Basic Directory Information Object Definition	File-set Identification Module	8.3.1	M
	Directory Information Module	8.3.2	U
Definition of Specific Directory Records	PATIENT keys	8.4.1	M
	STUDY keys	8.4.2	M
	SERIES keys	8.4.3	M
	IMAGE keys	8.4.4	M

¹ M=Mandatory, C=Conditional, U=User option

8.1.2 Media Storage XA IOD Modules

Table 6

Object	Module / key	Reference	Usage ¹
DICOM File Meta Information		8.2.2	M
XA Information Object Definition	XA IOD Modules	8.1.3	M

¹ M=Mandatory, C=Conditional, U=User option

8.1.3 XA IOD Modules

Table 7

Information Entity	Module	Reference	Usage ¹
Patient	Patient Module	8.5.1	M
Study	General Study Module	8.5.2	M
Study	Patient Study Module	8.5.3	U
Series	General Series Module	8.5.4	M
Equipment	General Equipment Module	8.5.5	M
Image	General Image Module	8.5.6	M
Image	Image Pixel Module	8.5.7	M
Image	Contrast/bolus Module	8.5.8	C
Image	Cine Module	8.5.9	C
Image	Multi-frame Module	8.5.10	C
Image	Frame Pointers Module	Not Used	U
Image	Mask Module	Not Used	C
Image	Display Shutter Module	Not Used	U
Image	Device Module	Not Used	U
Image	Therapy Module	Not Used	U
Image	X-ray Image Module	8.5.11	M
Image	X-ray Acquisition Module	8.5.12	M
Image	X-ray Collimator Module	Not Used	U
Image	X-ray Table Module	Not Used	C
Image	XA Positioner Module	8.5.13	M
Image	Overlay Plane Module	Not Used	U
Image	Multi-Frame Overlay Module	Not Used	C
Image	Curve Module	8.5.14	C (Note)
Image	Modality LUT Module	Not Used	C/U
Image	VOI LUT Module	8.5.15	U
Image	SOP Common Module	8.5.16	M

¹ M=Mandatory, C=Conditional, U=User option
Note : Always set when ECG data is available

8.2 DICOM File Meta Information

8.2.1 DICOM File Meta Information of Directory IOD

Table 8

Attribute Name	Tag	Type	Attribute Description
File Preamble	No Tag	1	Always set
DICOM Prefix	No Tag	1	Always set ("DICM")
Group Length	(0002, 0000)	1	Always set
File Meta Information Version	(0002, 0001)	1	Always set (0x0001)
Media Storage SOP Class UID	(0002, 0002)	1	Always set ("1.2.840.10008.1.3.10")
Media Storage SOP Instance UID	(0002, 0003)	1	Always set
Transfer Syntax UID	(0002, 0010)	1	Always set ("1.2.840.10008.1.2.1")
Implementation Class UID	(0002, 0012)	1	Always set

8.2.2 DICOM File Meta Information of XA IOD

Table 9

Attribute Name	Tag	Type	Attribute Description
File Preamble	No Tag	1	Always set
DICOM Prefix	No Tag	1	Always set ("DICM")
Group Length	(0002, 0000)	1	Always set
File Meta Information Version	(0002, 0001)	1	Always set (0x0001)
Media Storage SOP Class UID	(0002, 0002)	1	Always set ("1.2.840.10008.5.1.4.1.1.12.1")
Media Storage SOP Instance UID	(0002, 0003)	1	Always set
Transfer Syntax UID	(0002, 0010)	1	Always set ("1.2.840.10008.1.2.4.70")
Implementation Class UID	(0002, 0012)	1	Always set
Implementation Version Name	(0002, 0013)	3	Always set

8.3 Basic Directory Information Object Definitions

8.3.1 File-set Identification Module

Table 10

Attribute Name	Tag	Type	Attribute Description
File-set ID	(0004, 1130)	2	Always set

8.3.2 Directory Information Module

Table 11

Attribute Name	Tag	Type	Attribute Description
Offset of the First Directory Record of the Root Directory Entity	(0004, 1200)	1	Always set
Offset of the Last Directory Record of the Root Directory Entity	(0004, 1202)	1	Always set
File-set Consistency Flag	(0004, 1212)	1	Always set
Directory Record Sequence	(0004, 1220)	2	Always set
>Offset of the Next Directory Record	(0004, 1400)	1C	Always set when condition is met
>Record In-use Flag	(0004, 1410)	1C	Always set when condition is met
>Offset of Referenced Lower-Level Directory Entity	(0004, 1420)	1C	Always set when condition is met
>Directory Record Type	(0004, 1430)	1C	Always set when condition is met
>Referenced File ID	(0004, 1500)	1C	Always set when condition is met
>Referenced SOP Class UID in File	(0004, 1510)	1C	Always set when condition is met
>Referenced SOP Instance UID in File	(0004, 1511)	1C	Always set when condition is met
>Referenced Transfer Syntax UID in File	(0004, 1512)	1C	Always set when condition is met

8.4 Definition of Specific Directory Records

8.4.1 PATIENT keys

Table 12

Attribute Name	Tag	Type	Attribute Description
Patient's Name	(0010, 0010)	2	Always set except for urgent patient
Patient ID	(0010, 0020)	1	Always set
Patient's Birth Date	(0010, 0030)	2	Length=0 when no entry is made
Patient's Sex	(0010, 0040)	2	Always set

8.4.2 STUDY keys

Table 13

Attribute Name	Tag	Type	Attribute Description
Study Date	(0008, 0020)	1	Always set
Study Time	(0008, 0030)	1	Always set
Study Description	(0008, 1030)	2	Length=0 when no entry is made
Study Instance UID	(0020, 000D)	1C	Always set
Study ID	(0020, 0010)	1	Always set
Accession Number	(0008, 0050)	2	Length=0 when no entry is made

8.4.3 SERIES keys

Table 14

Attribute Name	Tag	Type	Attribute Description
Modality	(0008, 0060)	1	Always set ("XA")
Series Instance UID	(0020, 000E)	1	Always set
Series Number	(0020, 0011)	1	Always set
Institution Name	(0008, 0080)	2	Always set
Institution Address	(0008, 0081)	2	Always set
Performing Physician's Name	(0008, 1050)	2	Length=0 when no entry is made

8.4.4 IMAGE keys

Table 15

Attribute Name	Tag	Type	Attribute Description
Instance Number	(0020, 0013)	1	Always set
Image Type	(0008, 0008)	1	Always set
Image Date	(0008, 0023)	3	Always set
Image Time	(0008, 0033)	3	Always set
Positioner Primary Angle	(0018, 1510)	3	Always set [degree]
Positioner Secondary Angle	(0018, 1511)	3	Always set [degree]
Image Comments	(0020, 4000)	3	Length=0 when no entry is made
Number of Frames	(0028, 0008)	3	Always set
Calibration Image	(0050, 0004)	2	Always set
Icon Image Sequence	(0088, 0200)	1	Always set
>Samples per Pixel	(0028, 0002)	1	Always set (0x0001)
>Photometric Interpretation	(0028, 0004)	1	Always set ("MONOCHROME2")
>Rows	(0028, 0010)	1	Always set (0x0100)
>Columns	(0028, 0011)	1	Always set (0x0100)
>Bits Allocated	(0028, 0100)	1	Always set (0x0008)
>Bits Stored	(0028, 0101)	1	Always set (0x0008)
>High Bit	(0028, 0102)	1	Always set (0x0007)
>Pixel Representation	(0028, 0103)	1	Always set (0x0000)
>Pixel Data	(7FE0, 0010)	1	Always set

8.5 XA Information Object Definitions

8.5.1 Patient Module

Table 16

Attribute Name	Tag	Type	Attribute Description
Patient's Name	(0010, 0010)	2	Always set except for urgent patient
Patient ID	(0010, 0020)	2	Always set
Patient's Birth Date	(0010, 0030)	2	Length=0 when no entry is made
Patient's Sex	(0010, 0040)	2	Always set
Patient Comments	(0010, 4000)	3	Length=0 when no entry is made

8.5.2 General Study Module

Table 17

Attribute Name	Tag	Type	Attribute Description
Study Instance UID	(0020, 000D)	1	Always set
Study Date	(0008, 0020)	2	Always set
Study Time	(0008, 0030)	2	Always set
Referring Physician's Name	(0008, 0090)	2	Length=0 when no entry is made
Study ID	(0020, 0010)	2	Always set
Accession Number	(0008, 0050)	2	Length=0 when no entry is made
Study Description	(0008, 1030)	3	Length=0 when no entry is made

8.5.3 Patient Study Module

Table 18

Attribute Name	Tag	Type	Attribute Description
Patient's Size	(0010, 1020)	3	Length=0 when no entry is made
Patient's Weight	(0010, 1030)	3	Length=0 when no entry is made

8.5.4 General Series Module

Table 19

Attribute Name	Tag	Type	Attribute Description
Modality	(0008, 0060)	1	Always set ("XA")
Series Instance UID	(0020, 000E)	1	Always set
Series Number	(0020, 0011)	2	Always set
Series Date	(0008, 0021)	3	Always set
Series Time	(0008, 0031)	3	Always set
Performing Physician's Name	(0008, 1050)	3	Length=0 when no entry is made
Series Description	(0008, 103E)	3	Always set

8.5.5 General Equipment Module

Table 20

Attribute Name	Tag	Type	Attribute Description
Manufacturer	(0008, 0070)	2	Always set
Institution Name	(0008, 0080)	3	Always set
Institution Address	(0008, 0081)	3	Always set
Station Name	(0008, 1010)	3	Always set
Manufacturer's Model Name	(0008, 1090)	3	Always set
Device Serial Number	(0018, 1000)	3	Always set
Software Versions	(0018, 1020)	3	Always set

8.5.6 General Image Module

Table 21

Attribute Name	Tag	Type	Attribute Description
Image Number	(0020, 0013)	2	Always set
Patient Orientation	(0020, 0020)	2C	Always Length=0
Image Date	(0008, 0023)	2C	Always set
Image Time	(0008, 0033)	2C	Always set
Image Type	(0008, 0008)	3	Always set
Acquisition Date	(0008, 0022)	3	Always set
Acquisition Time	(0008, 0032)	3	Always set
Image Comments	(0020, 4000)	3	Length=0 when no entry is made

8.5.7 Image Pixel Module

Table 22

Attribute Name	Tag	Type	Attribute Description
Samples per Pixel	(0028, 0002)	1	Always set (0x0001)
Photometric Interpretation	(0028, 0004)	1	Always set ("MONOCHROME2")
Rows	(0028, 0010)	1	Always set (0x0400 or 0x0200)
Columns	(0028, 0011)	1	Always set (0x0400 or 0x0200)
Bits Allocated	(0028, 0100)	1	Always set (0x0008)
Bits Stored	(0028, 0101)	1	Always set (0x0008)
High Bit	(0028, 0102)	1	Always set (0x0007)
Pixel Representation	(0028, 0103)	1	Always set
Pixel Data	(7FE0, 0010)	1	Always set

8.5.8 Contrast/Bolus Module

Table 23

Attribute Name	Tag	Type	Attribute Description
Contrast/Bolus Agent	(0018, 0010)	2	Length=0 when no entry is made
Contrast/Bolus Route	(0018, 1040)	3	Length=0 when no entry is made
Contrast/Bolus Volume	(0018, 1041)	3	Length=0 when no entry is made
Contrast Flow Rate(s)	(0018, 1046)	3	Length=0 when no entry is made

8.5.9 Cine Module

Table 24

Attribute Name	Tag	Type	Attribute Description
Frame Time	(0018, 1063)	1C	Always set

8.5.10 Multi-frame Module

Table 25

Attribute Name	Tag	Type	Attribute Description
Number of Frames	(0028, 0008)	1	Always set
Frame Increment Pointer	(0028, 0009)	1	Always set (0x00181063)

8.5.11 X-ray Image Module

Table 26

Attribute Name	Tag	Type	Attribute Description
Frame Increment Pointer	(0028, 0009)	1C	Always set (0x00181063)
Image Type	(0008, 0008)	1	Always set
Pixel Intensity Relationship	(0028, 1040)	1	Always set ("DISP" or "LIN")
Samples per Pixel	(0028, 0002)	1	Always set (0x0001)
Photometric Interpretation	(0028, 0004)	1	Always set ("MONOCHROME2")
Bits Allocated	(0028, 0100)	1	Always set (0x0008)
Bits Stored	(0028, 0101)	1	Always set (0x0008)
High Bit	(0028, 0102)	1	Always set (0x0007)
Pixel Representation	(0028, 0103)	1	Always set
Reference Image Sequence	(0008, 1140)	1C	Not set when Image type(0008,0008) Value 3 is "SINGLE PLANE"
>Reference SOP Class UID	(0008, 1150)	1C	Always set when Reference Image Sequence is present
>Reference SOP Instance UID	(0008, 1155)	1C	Always set when Reference Image Sequence is present

8.5.12 X-ray Acquisition Module

Table 27

Attribute Name	Tag	Type	Attribute Description
KVP	(0018, 0060)	2	Always set [kV]
Radiation Setting	(0018, 1155)	1	Always set
X-ray Tube Current	(0018, 1151)	2C	Always set [mA]
Exposure Time	(0018, 1150)	2C	Always set [msec]
Average Pulse Width	(0018, 1154)	3	Always set [msec]
Intensifier Size	(0018, 1162)	3	Always set [mm]
Field of View Shape	(0018, 1147)	3	Always set("ROUND ")
Field of View Dimension(s)	(0018, 1149)	3	Always set [mm]
Imager Pixel Spacing	(0018, 1164)	3	Always set [mm]

8.5.13 XA Positioner Module

Table 28

Attribute Name	Tag	Type	Attribute Description
Distance Source to Detector	(0018, 1110)	3	Always set [mm]
Estimated Radiographic Magnification Factor	(0018,1114)	3	Always set
Positioner Motion	(0018, 1500)	2C	Always set ("STATIC")
Positioner Primary Angle	(0018, 1510)	2	Always set [degree]
Positioner Secondary Angle	(0018, 1511)	2	Always set [degree]

8.5.14 Curve Module

Table 29

Attribute Name	Tag	Type	Attribute Description
Curve Dimensions	(5000, 0005)	1	Always set
Number of Points	(5000, 0010)	1	Always set
Type of Data	(5000, 0020)	1	Always set
Axis Units	(5000, 0030)	3	Always set
Data Value Representation	(5000, 0103)	1	Always set
Curve Data Descriptor	(5000, 0110)	1C	Always set
Coordinate Start Value	(5000, 0112)	1C	Always set
Coordinate Step Value	(5000, 0114)	1C	Always set
Curve Data	(5000, 3000)	1	Always set

Note : This module is set only if ECG data is available.

8.5.15 VOI LUT Module

Table 30

Attribute Name	Tag	Type	Attribute Description
Window Center	(0028, 1050)	3	Always set
Window Width	(0028, 1051)	1C	Always set

8.5.16 SOP Common Module

Table 31

Attribute Name	Tag	Type	Attribute Description
SOP Class UID	(0008, 0016)	1	Always set
SOP Instance UID	(0008, 0018)	1	Always set